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Dated: 9/22/08 Name of Person Certifying: Olimpia Jakubowska-Wrobel Printed Name: Olimpia Jakubowska-Wrobel

Docket No. ECV-5539CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Huynh, et al.	Group Art Unit: 3738
Application No.: 10/802,314	Examiner: Brian E. Pellegrino
Filing Date: March 17, 2004	Confirmation No.: 3894
For: LOW-PROFILE HEART VALVE SEWING RING AND METHOD OF USE	**Customer Number: 30452**

Mail Stop APPEAL
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. §41.37

Dear Sir:

This is an appeal from the final rejections of claims 1-21 in the FINAL Office Action dated March 20, 2008. For the reasons discussed below, Applicants request reversal of the rejection and allowance of the claims.

The Notice of Appeal was filed on May 20, 2008.

The following comply with the subparts of 37 CFR §41.37(c)(1):

i.

REAL PARTY IN INTEREST

The real party in interest is Edwards Lifesciences Corporation of Irvine, California.

ii.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

iii.

STATUS OF THE CLAIMS

Claims 1-21 as listed in the attached claims Appendix are rejected.

iv.

STATUS OF AMENDMENTS

No amendments have been filed after the FINAL Office Action.

v.

SUMMARY OF CLAIMED SUBJECT MATTER

The application at issue discloses a sewing ring for prosthetic heart valves. The sewing ring is attached to a periphery of a stent and is configured to move between two stable positions, so as to be "bi-stable."

Claim 1 provides a sewing ring attached to a generally annular periphery of a prosthetic heart valve having an inflow end and an outflow end, the sewing ring being suture-permeable and configured to pivot between bi-stable positions, including a first position extending generally toward the outflow end of the valve to a second position extending generally toward the inflow end of the valve.

Exemplary support for claim 1 can be found in Figures 11-13, and in paragraphs [0059-0072] of Publication No. 2004/0176839. Structural variants and methods of use are shown in Figs. 14-17, as described in paragraphs [0073-0080]. Support for dependent claims 2-10 can be seen in Figs. 13-15, as described in paragraphs [0059-0075].

Claim 11 provides a prosthetic heart valve having an inflow end and an outflow end and including a generally annular stent and a suture-permeable sewing ring attached thereto. The

sewing ring is configured to pivot between bi-stable positions, including a first position extending generally toward the outflow end of the valve to a second position extending generally toward the inflow end of the valve.

Exemplary support for claim 11 can be found in Figures 11-13, and in paragraphs [0059-0072] of Publication No. 2004/0176839. Structural variants and methods of use are shown in Figs. 14-17, as described in paragraphs [0073-0080]. Support for dependent claims 12-21 can be seen in Figs. 13-15, as described in paragraphs [0059-0075].

vi.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-8 and 11-19 are not patentable under 35 U.S.C §102(b) as being anticipated by Totten, et al. (USPN 4,477,930, hereinafter, "Totten").

Whether claims 1-7 and 11-19 are not patentable under 35 U.S.C §102(b) as being anticipated by Vanney, et al. (USPN 5,843,179, hereinafter, "Vanney").

Whether claims 9 and 20 are not patentable under 35 U.S.C §103(a) as being obvious over Totten in view of Huynh, et al. (USPN 5,928,281, hereinafter, "Huynh").

Whether claims 10 and 21 are not patentable under 35 U.S.C §103(a) as being obvious over Totten in view of Reichart, et al. (USPN 4,626,255, hereinafter, "Reichart").

vii.

ARGUMENT

Are claims 1-8 and 11-19 anticipated by Totten?

The same claims were previously pending in parent application Serial No. 09/585,098, filed on June 1, 2000. In a telephonic interview dated June 9, 2003 between Examiner Pellegrino and Chris James (previously of record), agreement was reached vis-à-vis Totten concerning the same claims as those presently pending. Specifically, the Examiner stated that "Totten was capable of pivoting between two positions, but the sewing ring could not hold its position in both

the outflow and inflow positions." Subsequently, an amendment dated June 11, 2003 was filed incorporating the substance of the interview into the claims, which caused Examiner Pellegrino to prepare a Notice of Allowance dated June 17, 2003, again repeating the reason for allowance.

For technical reasons the parent application was expressly abandoned in favor of the instant application, though the same allowed claims were presented on the filing date of March 17, 2004. More than three years later, the present Office Action dated June 20, 2007 was prepared by Examiner Pellegrino which reiterates the original rejection on the basis of Totten. Applicants see no new reasoning which would change the previous indication of allowance. The original rejection has simply been repeated, with slight modifications, and the allowable disposition removed. Applicants object to the retraction of the allowance without anything new.

In any event, Applicants maintain that Totten does not disclose or suggest a sewing ring, or valve having a sewing ring that is configured to pivot or move between bi-stable first and second positions, respectively, toward the inflow end and the outflow end of the valve. Note that bi-stable means that the element moves between two stable positions.

Prior to the addition of tissue leaflets, a cloth-covered stent and sewing ring of Totten are shown in Figs. 7 and 8 below:

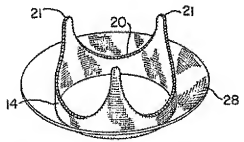

FIG. 7

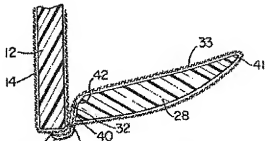

FIG. 8

The discussion of the construction includes the following passage:

> By reference to FIG. 7, it will be noted that the sewing ring 28 is of annular configuration and in cross-section tapers from a flat inner edge 40 outwardly to a somewhat pointed extremity 41. In addition, *to encourage the ring to lay smoothly when the skirt portions are pulled over it in a manner to be described and so as to be angled somewhat upwardly toward the post end of the stent*, a corner 42 is trimmed off of the inner edge so as to form a beveled edge along the upper corner of the flat surface portion

> 40. The sewing ring is inserted between the skirt portions 32 and 33 with the bottom corner of the ring resting against the second base stitch 38 and the trimmed or upper corner 42 facing the posts 19 of the stent. (Col. 5, lines 43-56, emphasis added)

The sewing ring 28 in Totten has a tapered profile and is attached to the valve stent by the surrounding fabric "so as to be angled somewhat upwardly toward the post end of the stent." Totten includes no mention or suggestion that the sewing ring 28 can pivot from the angled orientation seen in Figure 8, let alone be pivoted into a second stable position extending generally toward the inflow end (the first stable position extending generally toward the outflow end of the valve is the one shown in Fig. 8).

The Examiner asserts that the sewing ring in Totten is movable between two positions "since it is made of an elastomer...and Fig. 8 illustrates that the sewing ring can pivot about the edge." In addition, the Examiner reasons that since the sewing ring is pliable "thus it can be interpreted to be bi-stable because of its flexibility and placement at a seam or edge as seen in Fig. 8." Later, in response to the previous arguments, Examiner Pellegrino asserts that Totten's sewing ring is "clearly capable of pivoting between two positions and would be stable in the first or second positions the sewing (sic) can be considered bi-stable."

The Examiner's assertions as to the capabilities of Totten's sewing ring are mere speculation. He speculates that because of the flexible nature of the sewing ring, and its construction in the valve, it must be able to pivot into another stable position. However, the description in Totten clearly states that the sewing ring is encouraged to lie smoothly when the skirt portions are pulled over it so as to be angled somewhat upwardly toward the post (outflow) end of the stent. This obviously means that the fabric skirt is pulled tight to maintain the illustrated angle of the sewing ring. While the pliability of the sewing ring of Totten will permit it to flex outward from the angled position shown, there is simply no basis for asserting that it can pivot or move into another stable position angled in the opposite direction (toward the inflow end). The Examiner provides nothing but his opinion as to what the sewing ring can do, even thought the description suggests otherwise.

One benefit of the pivoting sewing ring of the present invention is that the implant procedure is facilitated, as seen in Figs. 16-17 and described in paragraphs [0076-0080]. If the same advantage were considered by Totten, one would assume it would be mentioned. However, in Col. 6, lines 53-59, the implant procedure is described as "conventional." There is no mention of pivoting the sewing ring into a second stable position, nor indeed of pivoting or moving the sewing ring at all. Note also that the closing pressures of blood on the valve in use would tend to maintain the illustrated angle of the sewing ring. Applicants submit that the sewing ring of Totten is simply not designed to pivot.

Examiner Pellegrino also states that the claim language having to do with pivoting or moving has not been given "much patentable weight since it is not supported by sufficient structure to warrant the presence of the functional language or recitations in the claim of giving meaning to pivotable feature being stable." And, "it can be said that the sewing ring of Totten pivots and is stable since it has an edge to cause the configuration to change directions." Applicants again object to the repeat of arguments made previously (see Office Action of 6/5/02 in S/N 09/585,098) and apparently overcome, only to have them re-emerge here in slightly different form. Moreover, the Examiner's standard is ambiguous, to say the least. The Examiner gives some weight to the "functional" terms, but not full weight, and apparently not enough to provide a structural limitation for the sewing ring. What does that mean? The claim terms "capable of pivoting or moving into bi-stable positions" would be clear to one of ordinary skill in the art. Characterizing the terms as functional is improper.

Similar to the situation where an element is "capable of extending from point A to point B", the valve on which the sewing ring of the present invention attaches has an inflow end and an outflow end, and the sewing ring is capable of pivoting from a stable position extending toward the inflow end to a stable position extending toward the outflow end. This language qualitatively and quantitatively describes the *structure* of the sewing ring and/or heart valve and sewing ring, or their interaction, so as to be sufficiently definite under 35 U.S.C. §112, and to provide patentable weight. This is true even though the claim terms do not explicitly explain the

structure that allows the pivoting movement, because the limitation could not be avoided when asserting the claim, which is a definite indication of patentable weight.

On point is In re Venezia, 530 F.2d 956, 189 USPQ 149 (CCPA 1976), in which the Court of Customs and Patent Appeals **reversed** a Board of Appeals decision that claim language similar to that at issue in the instant application should be given no weight. The court cited several examples, including one in claim 31 that called for "'a pair of sleeves... each sleeve of said pair *adapted to be fitted* over the insulating jacket of one of said cables.' Rather than being a mere direction of activities to take place in the future, this language imparts a structural limitation to the sleeve. Each sleeve is so structured or dimensioned that it can be fitted over the insulating jacket of a cable. A similar situation exists with respect to the 'adapted to be affixed' and 'adapted to be positioned' limitations in the third and fourth paragraphs of claim." Applicants see no conceptual difference between the phrase "adapted to be positioned" and the phrase in claims 1 and 11 "configured to pivot."

The MPEP is in agreement. Consider the following sections, and in particular the portions emphasized:

> 2173.01 Claim Terminology
> A fundamental principle contained in 35 U.S.C. §112, second paragraph is that Applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as the terms are not used in ways that are contrary to accepted meanings in the art. Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the Court in In re Swinehart, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), *a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.* (emphasis added)

> 2173.05(g) Functional Limitations
> A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). *There is nothing inherently wrong with defining some part of an invention in functional terms.* Functional language does not, in and of itself, render a claim improper. In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. *A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.* Whether or not the functional limitation complies with 35 U.S.C. 112, second paragraph is a different issue from whether the limitation is properly supported under 35 U.S.C. 112, first paragraph or is distinguished over the prior art. A few examples are set forth below to illustrate situations where the issue of whether a functional limitation complies with 35 U.S.C. 112, second paragraph was considered.

It was held that the limitation used to define a radical on a chemical compound as "incapable of forming a dye with said oxidizing developing agent" although functional, was perfectly acceptable because it set definite boundaries on the patent protection sought. In re Barr, 444 F.2d 588, 170 USPQ 33 (CCPA 1971).

In a claim that was directed to a kit of component parts capable of being assembled, the Court held that *limitations such as "members adapted to be positioned"* and "portions . . . being resiliently dilatable whereby said housing may be slidably positioned" *serve to precisely define present structural attributes of interrelated component parts of the claimed assembly.* In re Venezia, 530 F.2d 956, 189 USPQ 149 (CCPA 1976).

Accordingly, even if the Examiner considers the claim terms at issue to be functional, they must still be considered to carry patentable weight. The question of whether the sewing ring in Totten, et al. inherently pivots or moves to different positions has already been addressed in prior amendments, and the conclusion was that it doesn't. Indeed, that seems to be the basis for Examiner Pellegrino's prior determination of patentability for the present claims.

Accordingly, Applicants assert that claims 1 and 11, and claims dependent thereon, are allowable over Totten.

Are claims 1-7 and 11-19 anticipated by Vanney?

Vanney discloses a sewing ring having a suture guard (e.g., 60 in Figs. 6A and 6B) that covers suture knots used to secure the sewing ring to an annulus. That is, the suture guard in each embodiment is a flange or flap of fabric on the proximal side of the sewing ring that allows the surgeon to cover exposed knots on the proximal side of the sewing ring with the guard. In

the embodiments cited by Examiner Pellegrino, the suture guard is spring loaded into a closed position, such as with spring element 62 in Figs. 6A and 6B.

Applicants note that a) the suture guard is not a sewing ring, b) does not pivot between positions toward the inflow and outflow ends of the ring, and c) is not bi-stable. As to a), the suture guard is a flap on a larger sewing ring. Claims 1 and 11 pertain to the entire sewing ring, not just a part of a sewing ring. As to b), the suture guards of Vanney in their closed positions extend radially outward, and may be opened toward the proximal end to expose the knotting process. Thus, the suture guards do not pivot like the sewing rings of the present claims toward both the inflow and outflow directions. At least one of the positions is exactly in the middle between the inflow and outflow directions. Finally, the suture guards of Vanney are not bi-stable. In the specific embodiments cited by the Examiner, the suture guards are instead biased into a single position, i.e., closed against the proximal side of the sewing rings.

Examiner Pellegrino responds that the suture guard of Vanney meets the claim limitations because it is also suture-permeable, and because we have not explicitly claimed that the sewing ring is "the entire sewing ring." The former point is conceded, the suture guard is indeed suture permeable – indeed it appears to be made of the same fabric piece as the rest of the sewing ring. That does not make it a sewing ring, however. As to the latter point, what about the suture guard makes it into a sewing ring? It is instead a flap that covers suture knots 34 that pass through the sewing cuff 68, as in Fig. 6A-6B (see Col. 5, lines 34-52). The suture guard 60 is too small to function as a sewing ring, and is not described as such. The claims recite a sewing ring, and a sewing ring is what is claimed, not a portion thereof. The Examiner improperly asserts that because the claims are not to the entire sewing ring they can be viewed as less than a sewing ring to permit the suture guard of Vanney to read on them. The claims do not state that a part of the sewing ring pivots, but instead that the "sewing ring" pivots.

Accordingly, claims 1 and 11, and claims dependent thereon, are allowable over Vanney.

Are claims 9 and 20 obvious over Totten in view of Huynh?

Whether or not the combination of Totten and Huynh would be made by one of skill in the art, Applicants maintain that Totten does not disclose a bi-stable sewing ring as claimed, and therefore claims 1 and 11 are allowable. The addition of elements from Huynh does not change the fact that claims 9 and 20 depend from allowable claims. Moreover, Applicants submit that to combine certain elements of Totten with Huynh is hindsight construction.

Are claims 10 and 21 obvious over Totten in view of Reichart?

Again, Applicants maintain that Totten does not disclose a bi-stable sewing ring as claimed, and therefore claims 1 and 11 are allowable, also rendering claims 10 and 21 allowable. Further, the examiner provides no basis for combination of certain elements of Totten and Reichart.

viii.

CLAIMS APPENDIX

Claims 1-21 currently pending are attached hereto as an appendix.

ix.

EVIDENCE APPENDIX

None.

x.

RELATED PROCEEDINGS APPENDIX

None.

PETITION FOR EXTENSION OF TIME TO RESPOND

Pursuant to 37 C.F.R. 1.136(a), Applicant hereby requests an extension of time for one month to respond to the above-referenced Office Action. The Commissioner is hereby authorized to charge the required fee of $ 120.00 to Deposit Account No. 50-1225 (Docket no.ECV5539CON). A duplicate copy of this sheet is enclosed.

FEES

The Commissioner is hereby authorized to charge the Appeal fee under 37 C.F.R. §§41.20(b)(2) to Deposit Account No. 50-1225 (ECV-5539CON).

If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, such as under 37 C.F.R. §§ 1.16 or 1.17, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 50-1225.

Respectfully submitted,

Date: September 22, 2008

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Appendix

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of claims:

The following is a complete listing of the claims:

1. (Original) A sewing ring attached to a generally annular periphery of a prosthetic heart valve having an inflow end and an outflow end, comprising:

a suture-permeable ring attached to the heart valve periphery and configured to pivot from a first position extending generally toward the outflow end of the valve to a second position extending generally toward the inflow end of the valve, wherein first and second positions are stable such that the sewing ring is bi-stable.

2. (Original) The sewing ring of claim 1, wherein the sewing ring comprises a suture-permeable insert ring and a fabric cover.

3. (Original) The sewing ring of claim 2, wherein the insert ring is substantially planar.

4. (Original) The sewing ring of claim 2, wherein the fabric covering the insert ring also covers a portion of the heart valve.

5. (Original) The sewing ring of claim 4, wherein the fabric covering both the insert ring and the portion of the heart valve also connects the ring to the heart valve periphery at a seam, and wherein the sewing ring pivots between the first and second positions about the seam.

6. (Original) The sewing ring of claim 1, wherein the suture-permeable ring is attached to the heart valve periphery along a line, and wherein the sewing ring pivots between the first and second positions about the line.

7. (Original) The sewing ring of claim 6, wherein the sewing ring comprises a suture-permeable insert ring and a fabric cover, and wherein the fabric covers the insert ring and connects the insert ring to the heart valve periphery at a seam, the seam defining the line about which the sewing ring pivots.

8. (Original) The sewing ring of claim 1, wherein the sewing ring includes a suture-permeable, generally frusto-conical insert ring and wherein the first and second positions correspond to the frusto-conical insert ring extending outward from the periphery in opposite axial directions.

9. (Original) The sewing ring of claim 8, wherein the insert ring includes alternating radially thick and thin regions facilitating pivoting of the sewing ring between the first and second positions.

10. (Original) The sewing ring of claim 8, wherein the insert ring has a radially undulating shape facilitating pivoting of the sewing ring between the first and second positions.

11. (Original) A prosthetic heart valve having an inflow end and an outflow end, comprising:

a generally annular stent, and

a suture-permeable sewing ring attached to a periphery of the stent so as to be moveable between two positions, wherein in the first position the sewing ring extends generally toward the outflow end of the valve and in the second position the sewing ring

extends generally toward the inflow end of the valve, wherein first and second positions are stable such that the sewing ring is bi-stable.

12. (Original) The heart valve of claim 11, wherein the sewing ring comprises a suture-permeable insert ring and a fabric cover.

13. (Original) The heart valve of claim 12, wherein the fabric covering the insert ring also covers a portion of the stent.

14. (Original) The heart valve of claim 13, wherein a single piece of fabric is used to completely cover both the insert ring and the stent.

15. (Original) The heart valve of claim 11, wherein the sewing ring attaches to the stent exclusively with a portion of fabric that also covers at least a portion of the sewing ring.

16. (Original) The heart valve of claim 15, wherein a seam is provided in the fabric defining a line of attachment between the sewing ring and the stent, and wherein the sewing ring pivots about the seam between the first and second positions.

17. (Original) The heart valve of claim 11, wherein the suture-permeable sewing ring is attached to the stent periphery along a line, and wherein the sewing ring pivots between the first and second positions about the line.

18. (Original) The heart valve of claim 17, wherein the sewing ring comprises a suture-permeable insert ring and a fabric cover, and wherein the fabric covers the insert ring and connects the insert ring to the stent periphery at a seam, the seam defining the line about which the sewing ring pivots.

19. (Original) The heart valve of claim 11, wherein the sewing ring includes a suture-permeable, generally frusto-conical insert ring and wherein the first and second positions correspond to the frusto-conical insert ring extending toward the outflow end and the inflow end of the valve, respectively.

20. (Original) The heart valve of claim 19, wherein the insert ring includes alternating radially thick and thin regions facilitating movement of the sewing ring between the first and second positions.

21. (Original) The heart valve of claim 19, wherein the insert ring has a radially undulating shape facilitating pivoting of the sewing ring between the first and second positions.